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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,073	02/21/2002	Yoichi Iimura	0425-0877P	9107
2292	7590	04/21/2005	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/069,073

Applicant(s)

IIMURA ET AL.

Examiner

Brenda L. Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10, 15 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-10 is/are allowed.
- 6) ☒ Claim(s) 15 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/27/04

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

RD

### **DETAILED ACTION**

Claims 1-10, 15 and 21 are pending in the application.

This action is in response to applicant's amendment filed December 27, 2004. Claims 1, 2, 4, 8, 10 and 15 have been amended, claims 11, 12, 16 and 17 have been canceled.

### ***Response to Amendment***

Applicant's arguments filed December 27, 2004 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 11, 12, 15-17 and 21 the applicant's amendments and remarks have been fully considered but they are not found persuasive. The applicants' stated that claims 11, 12, 16 and 17 have been canceled. With respect to claim 15, which is a medical composition the applicants stated that "the M.P.E.P. states that when a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use". Hence, claim 15 is included in the rejection under 35 U.S.C. § 112, first paragraph where the enablement with respect to the use of the compounds has not been established as of yet.

With regards to claim 21, the applicants' emphasis is that claim 21 is directed to treating types of senile dementia or cerebrovascular dementia. The applicants reference several articles for support where inhibitors of acetylcholinesterase as used to treat Alzheimer's disease. As stated in the last office action, any article used to

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establish enablement of the applicants invention at the time of filing must be public knowledge prior to the filing date thus, the reference titled "Cholinesterase Inhibitors of Alzheimer's Disease" John C. Morris cannot be used to support enablement at the time of filing.

The applicants further supply two other references published in 1998 where the use of acetylcholinesterases are linked to Alzheimer's disease. As stated in the last office action, it is known that the treatment of Alzheimer's disease has been linked to acetylcholinesterase inhibitors, but the scope of the applicants method claim is to treating or **ameliorating** various types of senile dementia or cerebrovascular dementia and not to the treatment of senile dementia of the Alzheimer's type.

Claims 15 and 21 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

2. With regards to the 35 USC § 112, second paragraph rejections of claims 1-20, labeled paragraph 3g) maintained in the last office action, the applicants' amendments and arguments have been fully considered but they are not found persuasive. The applicants' stated that they herein incorporate the remarks above regarding the enablement rejection and that the scope of diseases or disorders as recited in claim 21 does "alter over time". The diseases embraced by senile dementia or cerebrovascular dementia may and/or does include other forms of dementia other than Alzheimer's disease.

Claim 21 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

3. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections of claims 10, 12 and 15, labeled paragraph 5 of the last office action, which are hereby **withdrawn**.

4. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection of claims 1-3, 5-7, 9, 11, 12, 15-17 and 21, labeled paragraph 6 of the last office action, which is hereby **withdrawn**.

5. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 103, obviousness rejection of claims 1-3, 5-7, 9, 11, 12, 15-17 and 21, labeled paragraph 7 of the last office action, which is hereby **withdrawn**.

#### ***Allowable Subject Matter***

6. Claims 1-10 are allowable over the prior art. However, the Applicants' attention is directed to U.S. Patent No. 6,844,440 (claims 44 and 45 such that instant formula (I) is where  $R^1$  is the formula and  $R^{3a}$  and  $R^{3b}$  are both methoxy,  $R^5$  is COOR specifically COOMe and COOEt, m is 1 and  $R^2$  is aralkyl, specifically benzyl), which while not competent as a reference against the instant claims, claims subject matter that is similar and/or identical to that claimed herein. **Two patents cannot issue on the same subject matter**, unless applicants can demonstrate that the claims are patentably


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distinct from the claims of this US patent, the only way to overcome this patent is by way of Interference proceedings or removal of the conflicting subject matter. See MPEP 2306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Brenda L. Coleman  
Primary Examiner Art Unit 1624  
April 17, 2005